GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:3759
ANSWERED ON:13.12.2000
IMPLEMENTATION OF GUIDELINES
DINESH CHANDRA YADAV;RAM JEEVAN SINGH

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether certain guidelines have been issued by the Government to regulate scientific research on humans;

(b) if so, the details thereof;

(c) the reasons for not considerating the enactment of a proper legislation governing such experiments on human beings; and

(d) the concrete steps taken/proposed to be taken to monitor the implementation of the guidelines and also to deal with any violation?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a) to (d) A Statement is laid on the Table of the House.

STATEMENT REFERRED TO IN REPLY TO LOK SABHA UNSTARRED QUESTION NO. 3759 FOR ANSWER ON 13.12.2000

The Indian council of Medical Research`s revised Ethical Guidelines for Bio-Medical Research on Human subjects has been released on 18.10.2000. The guidelines contain, inter-alia a statement on General Principles of Ethical considerations, chapters on `Ethical Review Procedures`; `General Ethical Issues`; Statement on Specific Principales for Clinica Evaluation of Drugs/ Devices/ Diagnostics/ Vaccines/ Herbal Remedies, Epidemiological Studies,Human Genetic Research, in Transplantation including Foetal Tissue Transplantation and Assisted Reproductive Technologies.

While most of the countries have a legislation for protection of animals used for scientific research, very few countries have the same for protection of human beings subjected to such research. The updation of the Ethical Guidelines brought out recently is a step in this direction.